

Message

From: Johnson, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3D10084D4CB247CEA03C9C43C770B7F5-MARION J. JOHNSON]
Sent: 7/30/2019 5:28:30 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Excellent. Thanks much!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Goodis, Michael
Sent: Tuesday, July 30, 2019 12:37 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Marion

Thanks for the heads up. I mentioned it to Rick during our general with him this morning and he is expecting it to come up during his next discussion with OGC.
I let him know that we are not following through on the request unless we hear otherwise.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, July 29, 2019 12:47 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: FW: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]
Importance: High

Mike,

You should probably be made aware of a request from AgLogic for EPA to release generic data to WHO. Many weeks ago, I was approached by Larry Hodges of Aglogic who had indicated that WHO-CCPR is desiring to see the data that was submitted to EPA in its evaluation of aldicarb. However, since AgLogic doesn't own the generic data, CCPR had suggested that AgLogic approach EPA to have the aldicarb data submitted directly to CCPR to assist in its continual review of the chemical. Knowing that the agency cannot just arbitrarily provide data without the required scrutiny under the regulations and after conferring with our FOIA office, I referred Larry Hodges to discuss the possibilities for the release of the data with Earl Ingram, FOIA Branch Chief.

As you can see from OGC's email below, there have already been a few conversations, some of which I've participated, with Bayer Corp., the data owner. It appears that OGC will be informing Rick of the current status, so I wanted you to be aware in the event Rick brings it to your attention. At this point, Bayer is reluctant to provide the data themselves, but Bayer indicated that they will be discussing the issue with AgLogic directly; this information comes from a telephone conversation between Bayer and the FOIA office of which I sat in.

Nevertheless, let me know if you have additional questions.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Sadowsky, Don
Sent: Monday, July 29, 2019 10:44 AM
To: Furlow, Calvin <Furlow.Calvin@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Knorr, Michele <knorr.michele@epa.gov>
Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Calvin and Earl --

Ex. 5 Attorney Client (AC)

Bob and Chris will be talking with Rick about the overall issues. Based on that discussion we will decide what to do.

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC) Is WHO/FAO waiting to hear from us before they proceed?

Please do inform AgLogic of Bayer's decision (though TBH I don't know why the two companies aren't talking to each other already), and that we're still considering whether providing the data to WHO/FAO is an option.

Don

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Furlow, Calvin <Furlow.Calvin@epa.gov>
Sent: Thursday, July 25, 2019 1:31 PM
To: Perlis, Robert <Perlis.Robert@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Perfect – thank you.

From: Perlis, Robert
Sent: Thursday, July 25, 2019 1:28 PM
To: Furlow, Calvin <Furlow.Calvin@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Calvin:

Thanks – somebody will get back to you next week.

Bob

Bob Perlis
Pesticides and Toxic Substances Law Office
Office of General Counsel
US EPA
(202) 564-5636

From: Furlow, Calvin
Sent: Thursday, July 25, 2019 12:15 PM
To: Perlis, Robert <Perlis.Robert@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Bob,
Yes, most certainly.

Thanks,
Calvin

From: Perlis, Robert
Sent: Thursday, July 25, 2019 12:12 PM
To: Furlow, Calvin <Furlow.Calvin@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Calvin:

Don is out this week (back on Monday, I believe). Ex. 5 Attorney Client (AC) and we would very much like to discuss this issue with Don before you take any steps here. Can you wait until early/mid next week? Please let me know. Thanks.

Bob

Bob Perlis
Pesticides and Toxic Substances Law Office
Office of General Counsel
US EPA
(202) 564-5636

From: Furlow, Calvin
Sent: Thursday, July 25, 2019 10:58 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Don,

After extended discussions, Bayer has concluded that it will not consent to EPA directly sharing its aldicarb tox and residue data with CCPR. It is Bayer's position that 1) AgLogic stands to commercially benefit from CCPR review and approval while circumventing appropriate compensation for the use of those data; and 2) CCPR has no mechanism under its authorities to protect from further disclosure any Bayer data it were to receive. Bayer intends to call AgLogic today but it does not anticipate that AgLogic will entertain a negotiated arrangement at this point.

We have not yet informed AgLogic of Bayer's decision to not consent, and we'd appreciate your advice on next steps.

Thanks,
Calvin

Calvin Furlow
Immediate Office
Information Technology and
Resources Management Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

Phone: 703-305-5229
furlow.calvin@epa.gov

From: Ingram, Earl
Sent: Monday, June 10, 2019 3:45 PM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>
Cc: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Thanks Don.

When RD contacted me initially, it was brought to me as a general question and I wasn't provided the background material.

From: Sadowsky, Don
Sent: Monday, June 10, 2019 3:36 PM
To: Ingram, Earl <Ingram.Earl@epa.gov>
Cc: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Ex. 5 Attorney Client (AC)

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Ingram, Earl
Sent: Monday, June 10, 2019 3:26 PM
To: Sadowsky, Don
Cc: Kaczmarek, Chris; Perlis, Robert; Dyner, Mark
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

We will contact Bayer and let you know what they say.

In the meantime, I have to respond to the requester, because I suspect we might not get an answer for a few days, do you have any suggestions?

From: Sadowsky, Don
Sent: Monday, June 10, 2019 2:49 PM
To: Ingram, Earl <Ingram.Earl@epa.gov>
Cc: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>
Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Ex. 5 Attorney Client (AC)

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Ingram, Earl
Sent: Monday, June 10, 2019 2:13 PM
To: Sadowsky, Don
Cc: Kaczmarek, Chris; Perlis, Robert; Dyner, Mark
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Thanks Don.

Ex. 5 Attorney Client (AC)

From: Sadowsky, Don
Sent: Monday, June 10, 2019 1:30 PM
To: Ingram, Earl <Ingram.Earl@epa.gov>

Cc: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dyner, Mark <dyner.mark@epa.gov>

Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Thank you very much, Earl, for running this by me before OPP did anything.

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Ingram, Earl
Sent: Monday, June 10, 2019 1:05 PM
To: Sadowsky, Don
Subject: FW: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

I wanted to run something pass you before I respond to the message below.

Ex. 5 Attorney Client (AC)

Here is the Codex Committee on Pesticide Residues (CCPR) members list and website <http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/>.

Ex. 5 Attorney Client (AC)

To receive registrant submitted data/studies, Section 10(g) of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires you to sign an Affirmation of Non-Multinational Status form. The form affirms the person requesting the pesticide data, does not work for or represent a pesticide producer. Please go to <https://www.epa.gov/foia/affirmation-non-multinational-status> for a copy of the affirmation form and an explanation of FIFRA Section 10(g). Section 10(g) also requires we notify the data owner to whom we released the data to. We will send you a list of all the studies submitted for each product, by COB this week. The studies are proprietary and cannot be posted or released for public access. Please keep in mind that the studies are proprietary and cannot be posted or released for public access. For explanation of FIFRA 10(g) and a copy of the Affirmation go to <https://www.epa.gov/foia/affirmation-non-multinational-status>.

You can submit your FOIA request via FOIAONLINE by going to <https://foiaonline.gov/foiaonline/action/public/home>.

From: Larry Hodges <larryhodges@meycorp.com>

Sent: Monday, June 10, 2019 11:57 AM

To: Ingram, Earl <Ingram.Earl@epa.gov>

Cc: Rate, Debra <Rate.Debra@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>

Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Mr. Earl Ingram,

As explained in the emails below, the Codex Committee on Pesticide Residues (CCPR) has scheduled aldicarb for review in 2020 and has requested that the registrant (AgLogic Chemical LLC) submit supporting toxicology and residue studies for review by the WHO and FAO. As AgLogic is a generic registrant we do not have access to the data submitted to EPA in support of the aldicarb registration and have requested that EPA provide the required studies to the CCPR.

Marion Johnson suggested that it may be possible for the required studies to be submitted directly to the CCPR through a FOIA request. Please let me know how we can get this process started.

Best Regards,

Larry Hodges, Ph.D.

Director of Regulatory Affairs

AgLogic Chemical LLC

Phone: 919-932-5800

From: Johnson, Marion [<mailto:Johnson.Marion@epa.gov>]

Sent: Wednesday, June 5, 2019 12:03 PM

To: Larry Hodges <larryhodges@meycorp.com>

Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>

Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Good afternoon, Larry!

I apologize for just responding to your inquiry, but we've had several recent and internal conversations within EPA/OPP about the possibilities of providing the requested data to support the aldicarb evaluation being conducted within WHO. At this point, it appears that the general consensus is that it's most appropriate to work through the Freedom of Information Act office within the Information Technology and Resources Management Division (ITRMD) at OPP. That determination was made based upon the requirements set forth under Section 10(g) of FIFRA, which, in part, restricts the availability of how studies/data submitted to agency can be released to a specific requestor.

For more specific information on this type of request, please contact Mr. Earl Ingram, Chief of OPP's FOIA activities at ingram.earl@epa.gov or by phone at 703 305-5456. Mr. Ingram has already been consulted by EPA staff within the Program concerning this inquiry, and should be familiar enough with your situation to provide further guidance. However, please let us know if we can be of further assistance once you've made contact with the FOIA office.

Best regards,

Marion J.

Marion J. Johnson, Jr.

Chief, Invertebrate-Vertebrate Branch 2

U.S. Environmental Protection Agency

Office of Pesticide Programs

Registration Division

(703) 305-6788 (tel)

(703) 308-0029 (fax)

Johnson.marion@epa.gov

Visit: <http://www.epa.gov/pesticides>

From: Larry Hodges <larryhodges@meycorp.com>

Sent: Wednesday, May 22, 2019 10:39 AM

To: Miller, David <Miller.DavidJ@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>

Subject: FW: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Mr. Miller,

Regarding the CCPR review of aldicarb, the email from Soren Madsen (WHO) suggests that it would be best if the EPA would provide the required studies to the CCPR and WHO for review by someone not from the EPA.

AgLogic is a generic registrant and our aldicarb registration is supported by studies that were conducted and submitted to the EPA by aldicarb's previous registrant. Although AgLogic Chemical has met the statutory requirements that allow EPA to rely upon all of the aldicarb studies in EPA's database we are not allowed to have copies of the actual studies that support our registration. As we are not able to submit these studies the CCPR or WHO for review, the alternative suggested by Mr. Madsen is for EPA to submit the studies directly to the CCPR and WHO.

As you suggested I emailed Marion Johnson and asked him to arrange a meeting to discuss the aldicarb review but have not heard back from him. Hopefully, Mr. Johnson will be able arrange a meeting in the near future.

Thanks and Best Regards,

Larry

From: MADSEN, Soren [<mailto:madsens@who.int>]

Sent: Wednesday, May 22, 2019 5:05 AM

To: Larry Hodges <larryhodges@meycorp.com>

Cc: Reichstein, Ian <ian.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>; VERGER, Philippe <vergerp@who.int>

Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry Hodges,

Of the 3 options for data submission regarding aldicarb to the JMPR, I think option 3 would be the most viable. JMPR will need original studies for the evaluation. In addition, it would be very useful to also have the US EPA registration document.

In order to avoid possible (or perceived) conflicts of interest, the JMPR secretariat seeks to assign monographers and reviewers that have not been directly involved in recent national evaluations of the assigned compound.

Regarding the possibilities for data submission, please refer to the previous calls for data available on the WHO website (<https://www.who.int/foodsafety/call-data/en/>).

Below is an extract from one of these calls:

"Governments, interested organizations, producers of these chemicals, and individuals are invited to submit data for the toxicological and the residues evaluations of the compounds listed."

The US National Authorities are of course welcome to submit data, should they wish to do so.

Best Regards,

Soren Madsen

Department of Food Safety and Zoonoses

World Health Organization

20, Avenue Appia, CH-1211 Geneva 27

Switzerland

Tel direct: + 41 22 791 36 97

From: VERGER, Philippe

Sent: Wednesday, April 17, 2019 7:46 AM

To: Larry Hodges <larryhodges@meycorp.com>; MADSEN, Soren <maidsens@who.int>

Cc: Reichstein, Ian <lan.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>

Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry

I forward your message to my colleague Soren Madsen who is the new WHO JMPR Secretary.

Best regards

Philippe

Dr. Philippe Verger

Advisor Food Safety

WHO/EMRO/CEHA



Le 15 avr. 2019 à 15:44, Larry Hodges <larryhodges@meycorp.com> a écrit :

Dear Dr. Verger and Mr. Reichstein,

I sent you the email immediately below requesting help in responding to the upcoming review of aldicarb. As AgLogic is a generic registrant we do not have access to the toxicology and residue studies that have been submitted to the US EPA in support of aldicarb. I made some suggestions on how we could possibly move forward and would like you thoughts on the best way to proceed.

Thanks and Best Regards,

Larry Hodges, Ph.D.

Director of Regulatory Affairs

AgLogic Chemical LLC

Phone: 919-932-5800

From: Larry Hodges

Sent: Tuesday, February 26, 2019 11:35 AM

To: VERGER, Philippe <vergerp@who.int>; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>

Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>

Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Dr. Verger and Mr. Reichstein,

It is my understanding that the toxicology and residue dossiers for aldicarb must be submitted by December 2019. AgLogic Chemical LLC can certainly meet this deadline and submit the data that we have developed on aldicarb. However, AgLogic is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and submitted to the US Environmental Protection Agency (US EPA) by aldicarb's previous registrant, Bayer CropScience.

Although AgLogic Chemical has met the statutory requirements that allow EPA to rely upon Bayer's aldicarb data, including payment of compensation to Bayer, we are not allowed to have copies of the actual studies that support registration. Therefore, we are not able to submit these studies the CCPR or WHO for review.

Since it is not possible for AgLogic to submit the toxicology and residue studies that support aldicarb, I would like to propose three possible alternatives:

1. The US EPA recently completed and published its registration review for aldicarb. This document reviews and discusses all data required to support aldicarb registration in the USA. We could submit this document in place of the studies.
2. Since the US EPA already has all of the supporting studies, the aldicarb reviews could be written by the US EPA's residue and toxicology experts that participate in the CCPR and WHO.
3. The US EPA could provide the required studies to the CCPR and WHO for review by someone not from the US EPA.

Please let me know how best to proceed.

Best Regards,

Larry Hodges, Ph.D.

Director of Regulatory Affairs

AgLogic Chemical LLC

Phone: 919-932-5800

From: VERGER, Philippe [<mailto:vergerp@who.int>]
Sent: Friday, October 26, 2018 10:21 AM
To: Larry Hodges <larryhodges@meycorp.com>; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry,

I am responding as I guess Australia is sleeping now... The date mentioned by Ian is to apply to the prioritization. My date 1 year later is to submit the full tox dossier.

Hope it helps

Philippe

Dr Philippe Verger MD, PhD
Department of Food Safety and Zoonoses
World Health Organization
20, Avenue Appia, CH-1211 Geneva 27
Switzerland

Tel direct: + 41 22 791 30 53

Ex. 6 cell phone

Website: <http://www.who.int/foodsafety/chem/en/>

From: Larry Hodges [<mailto:larryhodges@meycorp.com>]
Sent: 26 October 2018 15:25
To: Reichstein, Ian; VERGER, Philippe
Cc: Miller, David; Niman, Aaron; Doherty, Michael; YongZhen.Yang@fao.org; Antoine Puech
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Mr. Reichstein,

Dr. Verger said the deadline for submission was December 2019. It was my understanding that Dr. Verger was referring to all data. Is the date for the residue data December 2018 and the date for the toxicology data December 2019?

Thanks for the clarification,
Larry

From: Reichstein, Ian [<mailto:Ian.Reichstein@agriculture.gov.au>]
Sent: Thursday, October 25, 2018 8:08 PM
To: Larry Hodges <larryhodges@meycorp.com>; VERGER, Philippe <vergerp@who.int>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry

Receipt of information to include against aldicarb should be lodged by 1 December 2018 for inclusion in the draft CCPR agenda paper.

I have moved the compound to the 2020 list.

Kind regards
Ian



Ian Reichstein
Director - National Residue Survey
Residues & Food | Exports Division
Department of Agriculture and Water Resources

Position number: 13107

~~Phone: 61 10 13 6322 5668~~

Ex. 6 cell phone

Location: M9.185 Marcus Clarke Building
18 Marcus Clarke Street CANBERRA ACT 2601 Australia
PO Box 858 CANBERRA ACT 2601 Australia

From: Larry Hodges [<mailto:larryhodges@meycorp.com>]
Sent: Friday, 26 October 2018 1:48 AM
To: VERGER, Philippe <vergerp@who.int>; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Dr. Verger and Mr. Reichstein,

Thank you for moving aldicarb from the 2019 agenda to the 2020 agenda.

Dr. Verger, please clarify if this is to be a follow up evaluation or a full toxicology evaluation. It is my understanding that only data not previously submitted to the JMPR need to be submitted and that the submission should focus on data relevant to determine the potential for public health concerns.

Also, can you tell me the deadline for submission of the studies that will be reviewed in 2020.

Mr. Reichstein, please let me know when you need for us to provide you with the spreadsheet with commodities supported.

Thank You,
Larry

From: VERGER, Philippe [<mailto:vergerp@who.int>]
Sent: Thursday, October 25, 2018 6:14 AM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Larry Hodges <larryhodges@meycorp.com>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry

The solution proposed by Ian is fine for me in particular if you are planning to submit a full tox (and not tax !) dossier. In practice I can remove the compound from the 2019 agenda.
Be aware that the compound was placed on the agenda for public health concern so you may consider also proposing residue data.

Best regards

Philippe Verger
WHO - OMS

Le 24 oct. 2018 à 23:05, Reichstein, Ian <Ian.Reichstein@agriculture.gov.au> a écrit :

Dear Larry

Thank you for clarifying the ongoing support for aldicarb.
I do recall our earlier conversation in regard to this compound. Unfortunately I had heard nothing on aldicarb until now and several reservations had been received in the interim.

In any case, the matter can be resolved immediately with aldicarb reinstated as a supported compound awaiting periodic review.
Noting the 2019 Schedule of periodic reviews has reached its quota, aldicarb will be placed as a confirmed listing for the 2020 Schedule.

For the CCPR Schedules and Priorities spreadsheet to which you refer, could you provide a data line (following the spreadsheet format) which I can cut and paste into the file.
This should include the commodities supported and the expected number of field trials to be submitted for each?

In regard to the tax data package, Dr Verger is best placed to advise.

I apologise for any confusion in this matter.

Fortunately in almost all cases, these matters are easily rectified.

Kind regards
Ian



Ian Reichstein
Director - National Residue Survey
Residues & Food | Exports Division
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From: Larry Hodges [<mailto:larryhodges@meycorp.com>]
Sent: Thursday, 25 October 2018 5:39 AM
To: vergerp@who.int; Reichstein, Ian <lan.Reichstein@agriculture.gov.au>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>;
Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine
Puech <antoinepuech@meycorp.com>
Subject: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Dr. Verger and Mr. Reichstein,

Aldicarb (177*) is listed as an unsupported compound in Annex 1 of the list of substances scheduled for follow up evaluation at the 2019 Extraordinary Joint FAO/WHO Meeting on Pesticide Residues (see attachment). This document indicates that the deadline for submission of the toxicology data is November 1, 2018.

Additionally, the 50th report of the CCPR, dated April 2018 (see attachment) stated on page 13 that Aldicarb (177*) was unsupported and would be reviewed by the WHO in 2019, presumably at the Extraordinary Meeting in Ottawa.

Would you please clarify/confirm:

- Is aldicarb on the agenda for the Extraordinary JMPR Meeting scheduled in Ottawa on May 7-17, 2019?
- If so, do we need to submit toxicology data by November 1, 2018? (Paragraph 145 from CCPR50 indicated that members/observers needed to commit to provide support/data prior to CCPR51. If so, can the follow up evaluation of aldicarb be rescheduled?)
- Is aldicarb on the 2019 CCPR (51st) meeting to be held in China on April 20-19?

In February 2016 we contacted Mr. Ian Reichstein (Chair of the CCPR Electronic Working Group on Priorities) and recently contacted Mr. David Miller (USA EPA) clarifying our support of aldicarb. AgLogic Chemical LLC is the only USA registrant of aldicarb and fully supports all registered uses and all USA tolerances and corresponding Codex MRLs. Specifically, the supported crops are cotton, dry bean, peanut, soybean, sweet potato, orange, grapefruit, lemon, lime, potato, and coffee.

As we are approaching the November 1, 2018 submission deadline, please let us know if aldicarb is scheduled for review in 2019 or if it can be rescheduled.

*Please note that both of the attached documents list aldicarb as compound 177 whereas previous CCPR and JMPR documents list aldicarb as compound 117.

Thank You,

Larry Hodges

Director of Regulatory Affairs

AgLogic Chemical LLC

Phone: 919-932-5800

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